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In The

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., *et al.*,

Petitioners,

v.

BAYER AG, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF THE PUBLIC PATENT FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICUS CURIAE*[1]

The Public Patent Foundation ("PUBPAT") is a not-for-profit legal services organization affiliated with the Benjamin N. Cardozo School of Law that aims to protect freedom in patent system. Specifically, PUBPAT represents the public interest against undeserved patents and unsound patent policy. PUBPAT has argued for sound patent policy before this Court, the Courts of Appeals for the Second, Eleventh and Federal Circuits, both houses of Congress, the U.S. Patent & Trademark Office (PTO), the United Nations, the European Union Parliament, the Australian Parliament, and many other national and international bodies. PUBPAT has also successfully challenged specific undeserved patents causing significant harm to the public through litigation and administrative proceedings. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

PUBPAT has an interest in this matter because the decision of this Court will have a significant effect

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[1] In accordance with Supreme Court Rule 37.6, *Amicus Curiae* states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amicus*, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Parties were timely informed of the intent to file this *amicus* brief, and the written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

on the public interest represented by PUBPAT. More specifically, PUBPAT has an interest in ensuring that patent holders are not allowed to undermine patent quality by paying competitors to drop challenges to their patents. Although technically an antitrust case, this matter involves the settlement of patent infringement litigation where the challenger had mounted a legitimate attack on the validity of the subject patent. The Court of Appeals below assumed that the patent – and in fact all patents – are valid, which is completely out of touch with reality. In truth, about half of all patents challenged in court are proven invalid and the PTO's own statistics concede that more than 90% of all issued patents have substantial questions regarding their validity.

As such, PUBPAT believes its brief, authored by a registered patent attorney and professor of patent law, addressing some of the underlying patent issues in this case provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. This is especially true since PUBPAT has particular experience with issues relating to patent quality.

SUMMARY OF ARGUMENT

Patent quality is the single most important issue in our patent system, because without it, our patent system risks losing all credibility and the support of the American people. We must, above all other goals,

ensure only deserving patents are issued and maintained. Thus, it should be more than plainly obvious that allowing patent holders to pay competitors to drop challenges to patents harms the public interest by eliminating one of the most important checks our American patent system has on patent quality, namely the challenging of important patents by commercially motivated parties. As such, patent holders should not be allowed to settle cases involving challenges to their patents with a substantial payment to the challenger of the patent in order to have the challenge withdrawn. In fact, encouraging challenges to patents that are of undeserved scope is a critical public service function and limits the government restraint of freedom embodied in a patent. This is a principle long recognized by this Court and adopted by Congress in passing the Hatch-Waxman scheme at the heart of this case.

Therefore, to protect the public from undeserved patents and anti-competitive settlements of patent infringement litigation whereby a potential competitor is offered a share of the monopoly profits that can be maintained if it drops its challenge to a patent and agrees to stay off the market, this Court should grant the petition for a writ of certiorari and correct the mistake made by the Second Circuit in this case.

REASONS FOR GRANTING THE PETITION

People unfamiliar with the patent system, including specifically the Court of Appeals in this case, are woefully unaware of the pathetic state of American patent quality. As a result, most people unfamiliar with the patent system tend to give patents entirely way too much credit. Rather than being rock-solid undeniable fortresses of legal dominance over a segment of technology, patents today give their owner nothing more than, at best, a fifty-fifty chance of having any exclusionary power at all. As such, the Court of Appeals' assumption that any patent has an exclusionary power equal to its full term over any product is without merit.

Instead of recognizing this fundamental truth of the patent system, the Court of Appeals instead chose to blindly adopt the position that all patents are to be presumed to have total exclusionary power over any product against which they are asserted for their entire term and, thus, any settlement of a patent infringement allegation that allows an accused product to enter the market prior to the patent's expiration is exempt from the competition laws. This conclusion is wrong and, if left undisturbed, will lead to substantial harm being caused to the American public through lower patent quality and reduced competition. To be sure, this effect will be felt not only in the pharmaceutical industry, but in many other industries as well. As such, the petition for a writ of *certiorari* should be granted.

I. PATENT QUALITY IS A CRITICAL PUBLIC INTEREST, AND WILL SUFFER IF PATENT HOLDERS CAN PAY OFF CHALLENGERS TO THEIR PATENTS

A. Patent Quality In The United States Today Is Extremely Poor

There are several sources to help determine the current level of quality for U.S. patents, and all of them paint a very clear picture that patent quality today in America is extremely poor. One source, an ongoing project of the University of Houston Law School, which is known for having one of the most reputable patent departments in the country, tracks the results of patent litigation and empirically categorizes those results according to the specific issues involved with each case. Patstats, available at www.patstats.org. Looking at their data shows that approximately 45% of all issued patents reviewed by courts in 2009 were found to have been undeserved. *See* Univ. of Houston Law Ctr. Inst. for Intellectual Prop. & Info. Law, Full Calendar Year 2009 Report, http://www.patstats.org/2009_full_year_posting.htm.

When looking at this data, there are some caveats to keep in mind. First, it could be argued that the rate at which patents asserted in litigation are determined to be invalid is not applicable to the general pool of all issued patents, since only about 1% of issued patents end up getting litigated to a decision on their merits. While this may be a valid point, it does not mean that the actual validity rate of issued patents is higher or lower than that of litigated

patents, because it is generally only the patent owner who can put a patent in litigation. Therefore, many issued patents do not get their validity challenged in litigation because the patent owner chooses not to assert the patent.

Second, even if these statistics are limited to just litigated patents, they are still extremely important because litigated patents tend to have a much greater significance to the public, on average, than non-litigated patents. John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 Georgetown Law Journal 435 (2004). To draw an analogy, if 45% of the people on death row who challenged their convictions were actually proven innocent, that wouldn't necessarily mean that 45% of all people on death row, much less 45% of all convicted criminals, were actually innocent (that ratio could be higher or lower), but the severity of each mistake regarding someone on death row is extreme nonetheless. Similarly, the technology involved with litigated patents is almost without exception extremely valuable, so any mistakes regarding the validity of those patents can cause severe harm in and of itself, regardless of the validity rate of issued patents overall.

Another source of information about patent quality is the PTO's own statistics relating to reexamination, which show that more than 90% of all requests for reexamination are granted, an action that requires a finding that a "substantial new question of patentability" exists. *Inter Partes Reexamination Filing Data –*

June 30, 2009, USPTO, www.uspto.gov/web/patents/documents/inter_partes.pdf ("*Inter Partes* Report") (95% of all requests for *inter partes* reexamination granted); *Ex Parte Reexamination Filing Data – June 30, 2009*, USPTO, www.uspto.gov/web/patents/documents/ex_parte.pdf ("*Ex Parte* Report") (92% of all requests for *ex parte* reexamination granted); 35 U.S.C. § 312. These statistics show that the overwhelming majority of patents issued by the PTO have "questionable" validity. Our patent office may not be a rubber stamp *per se*, but it is pretty close to one in reality.

Looking deeper, the PTO's data shows that 95% of patents challenged through the *inter partes* reexamination process, which allows for ongoing participation by the challenger, are canceled or changed, while more than 75% of patents challenged through the *ex parte* reexamination process, which does not allow the challenger to participate after submitting the initial request, have their claims canceled or changed. *Inter Partes* Report (all claims canceled 60%, claims changed 35%); *Ex Parte* Report (all claims cancelled 11%, claims changed 64%). This is absolutely disgusting. Our patent system should be ashamed that it has been perverted to the point of producing patents with such low quality. The American people deserve better.

One way to confirm how grim the state of affairs is for U.S. patent quality is to compare our system's patent application outcomes to those of other well respected patent offices. Firstly, the USPTO ultimately grants patents from 85% of all original applications,

while that rate is only 64% in Japan. Cecil D. Quillen, Ogden D. Webster, and Richard Eichman, *Continuing Patent Applications and Performance at the U. S. Patent and Trademark Office-Extended*, 12 Fed. Cir. B.J. 35 (2002). However, a better comparative picture is drawn by a study of roughly 70,000 issued U.S. patents and their corresponding foreign applications, which found that counterparts to patent applications issued in the U.S. were only issued by the European Patent Office 72.5% of the time and by the Japan Patent Office only 44.5% of the time. Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, *Disharmony in International Patent Office Decisions*, 16 Fed. Cir. B.J. 679 (2006). This evidence shows that the U.S. Patent Office is indeed granting a very disproportionally high number of patents and not implementing procedures to ensure patent quality to the same level as other developed nations. For one, most of the world permits the filing of pre-grant oppositions to patent applications by members of the public. We have no such procedure here in America, where pre-grant oppositions are expressly banned.

B. Undeserved Patents Cause Substantial Public Harm

Patents that are undeserved can cause substantial harm to the American public, because an issued patent – regardless of its true legitimacy – can be used to threaten and impede otherwise permissible, socially desirable, conduct. The threat of having to incur the costs and potential liability of a patent

lawsuit is one that few individuals or small businesses can withstand, even if the patent is of doubtful validity. This chilling effect, when caused by a patent that would be ruled invalid if challenged, provides no social benefit to the American people, because the patent contains nothing new; its invalidity means that whatever it claims or describes was either already known or was obvious in light of what was already known. This effect can be devastating to the American people.

For example, there have been several patents that were used to preclude competition in markets worth billions of dollars that were later proven to be undeserved. *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001) (patent preventing competition to $1.6B per year cancer treatment, Taxol, proven invalid); *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955 (Fed. Cir. 2001) (patent barring alternatives to $2.9B per year antidepressant medication, Prozac, proven invalid). Poor patent quality is also partially to blame for the intensive increase in patent litigation, the dramatically higher cost of patent litigation, and the rapid rise of patent speculators – mostly contingency fee patent litigators – who are more than willing to assert questionable patents against large and small commercial actors for the chance of reaping windfall judgments.

Further, the over-patenting that results from low patent quality leads to thickets of patents that choke first inventors with countless small improvement patents claimed by others. In what is akin to

grade-inflation, by granting too many people too many patents, those inventors who legitimately did derive wonderful new technology get less credit than they deserve because of all the other patents that are issued in the related field. This results in less incentive for the truest of innovators amongst us and instead encourages investments in making minor improvements to the inventions of others. These are, unfortunately, but a few of the many harmful effects that poor patent quality is having on the American public today.

C. Challenges To Undeserved Patents Must Be Encouraged

Patents are, by nature, government-granted restraints on freedom. Every Tuesday (the day of the week the Patent Office issues new patents) there are roughly 4,500 new things that no American is allowed to do, and there is no fair use defense to patent infringement like with copyright and trademark. Thus, only those who love big government and the meddling of Washington bureaucrats into the lives and affairs of American citizens and American businesses can inherently want a bigger, stronger patent system. Thomas Jefferson, the founder of our patent system, was right to be skeptical of patents when he labeled them a necessary evil which must be short-lived and strictly limited to only those few situations when they are absolutely necessary.

Aligned with this cautious perspective on patents, this Court has repeatedly recognized that maintaining high patent quality is of the utmost importance in ensuring that the patent system benefits the American people. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007) ("[T]he results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.") (citing U.S. Const., art. I, § 8, cl. 8). Undeserved patents substantially harm the public by imposing the high costs of exclusive rights without providing any corresponding advance in the state of the art. The public bears the burden of the chilling effect of meritless patents without receiving any commensurate benefit upon their expiration. Invalid patents pose a dead-weight economic loss for society, not to mention the inhibition on any civil liberties that may be intertwined with the unjustifiably claimed technology.

Commercial entities are frequently the best suited and most incentivized to challenge patents held by their competitors. Thus, allowing patent holders to bribe competitors to not challenge their patents most assuredly results in a decrease of patent quality. Commercial actors will undoubtedly strategically act in collusion to maximize the profit that can be derived from a patent so that they can then share that maximal profit between themselves. This is much better for the commercial entities than entering into competition where such rents will be naturally whittled

away for the public benefit. The American people deserve a patent system that is empowered with thorough and meaningful challenges to patents brought by competitors. Without such, try as they might to make their best decisions, the public will be forced to bear the burden of the PTO's continued inability to ensure that only deserving patents are issued. Thus, the Court of Appeals' decision permitting patentees to pay competitors to drop challenges to their patents is contrary to the substantial public interest in maintaining high patent quality, and should be reversed.

This Court has recognized that discouraging anticompetitive settlements of patent infringement cases has, in itself, a pro-competitive effect. Accused infringers who prove a patent invalid perform an important public service by correcting the PTO's errors on their own nickel. *See Lear v. Adkins*, 395 U.S. 653, 670 (1969) (explaining that if those "with economic incentive to challenge the patentability of an inventor's discovery" do not do so, "the public may continually be required to pay tribute to would be monopolists without need or justification"); *Pope Mfng. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("[i]t is as important to the public that competition should not be repressed by worthless patents as that the patentee of a really valuable invention should be protected in his monopoly"). Even those who try but fail to prove a patent invalid perform a public service by narrowing uncertainty as to the patent's validity, thus encouraging others to respect it. *Kloster Speedsteel*

AB v. Crucible, Inc., 793 F.2d 1565, 1581 (Fed. Cir. 1986).

Further, the Court of Appeals failed to recognize that application of sound antitrust law and policy comports with the policies implemented in the Hatch-Waxman Act. The entire point of Hatch-Waxman was to encourage and protect competition in the pharmaceutical industry, which it did in two principal ways: (i) making it easier for competition to already available products to be introduced; and (ii) encouraging new innovative products to be brought to market by strengthening patent rights. *See* H. Rep. No. 98-857(I). Unfortunately, pharmaceutical companies, both brand and generic, have been able to circumvent the pro-competitive intent of Hatch-Waxman to fashion a sharing of monopoly profits made by one of them instead of competing with one another in the marketplace because it is "littered with loopholes." Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227 (2001). By condoning net-anticompetitive gaming of the Hatch-Waxman regime through patent infringement litigation settlement agreements, the Court of Appeals' decision will frustrate, not promote, Hatch-Waxman's goals.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for a writ of *certiorari*.

Respectfully submitted,

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